



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration  
Rockville MD 20857

JUL - 2 1998

**TRANSMITTED VIA FACSIMILE**

Judy Gordon, DVM  
Vice President, Research and Development  
Bausch & Lomb Surgical, Chiron Vision Products  
9342 Jeronimo Road  
Irvine , CA 92618-1903

**RE: NDA 20-569**  
Vitrasert Sterile Intravitreal Implant with Cytovene  
MACMIS ID # 6803

Dear Dr. Gordon:

This letter is in reference to Bausch & Lomb Surgical's (B&L) submission, dated June 19, 1998, of promotional materials under cover of Form FDA 2253 for Vitrasert Sterile Intravitreal Implant with Cytovene. The submission included a brochure identified as 98029 and a reprint carrier identified as 98008. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these promotional materials and has concluded that they are lacking in fair balance or are otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

This promotional labeling fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. Although information is presented regarding the potential complications associated with intraocular surgery, the information is presented in a manner that minimizes its importance and readability. Further, B&L has not included information from the approved product labeling regarding warnings, and precautions associated with the use of this product.

B&L should immediately cease the dissemination of these violative promotional materials and all similar promotional materials that are lacking in fair balance.

B&L's written correspondence regarding this matter should be received by DDMAC no later than July 16, 1998.

Judy F. Gordon, DMV  
Bausch & Lomb Surgical, Chiron Vision Products  
NDA 20-569

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Please direct your correspondence to undersigned by facsimile (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds B&L that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 6803 and NDA 20-569.

Sincerely,

/S/

Warren F. Rumble  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications